

# AEON™ Endoscopic Stapler Instructions for Use



**REVIEW THE FOLLOWING INFORMATION CAREFULLY BEFORE USING THE DEVICE.**

Instructions for Use may also be found at [www.lexington-med.com/IFU](http://www.lexington-med.com/IFU)

**NOTE:** These Instructions for Use are designed to assist in the use of this product - they are not a reference for surgical techniques.

**WARNING: The AEON™ Endoscopic Stapler Handle is provided STERILE and intended for use in a SINGLE PROCEDURE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS.**

**WARNING: The AEON™ Endoscopic Stapler Reload is provided STERILE and intended for SINGLE USE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS. Reuse, re-processing, or re-sterilization may compromise device integrity and could lead to patient injury, illness, or death.**

## DEVICE DESCRIPTION


The AEON™ Endoscopic Stapler places two triple-staggered rows of Titanium staples while simultaneously transecting between the two triple-staggered rows of staples. The size of the staples and staple line length are based on the selection of the Stapler Reload 2.25mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, 4.0mm/60mm, and 5.0mm/60mm. The AEON™ Endoscopic Stapler Handle will accommodate all AEON™ Endoscopic Stapler Reloads.


The AEON™ Endoscopic Stapler Handle and AEON™ Endoscopic Stapler Reloads 2.25mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, and 4.0mm/60mm are designed for introduction through a 12mm trocar, or larger with use of a converter. The AEON™ Endoscopic Stapler Reload 5.0mm/60mm must be inserted through a 15mm trocar.

The AEON™ Endoscopic Stapler Handle may be reloaded and fired up to 25 times in a single procedure.

**NOTE:** When using the instrument with a 5.0mm/60mm reload, the instrument **MUST** be inserted into a 15mm trocar. A smaller size trocar will not accept the 5.0mm/60mm reload.

These Instructions for Use pertain to the following products:

ENDOSCOPIC STAPLER HANDLES	PRODUCT CODE	SHAFT LENGTH
	AESH160	MEDIUM (160mm)
	AESH260	LONG (260mm)

ENDOSCOPIC STAPLER RELOADS	PRODUCT CODE	OPEN STAPLE HEIGHT	STAPLE LINE LENGTH	CLOSED STAPLE HEIGHT
	AESR45T	2.25mm	45mm	1.0mm
	AESR60T	2.5mm	60mm	1.0mm
	AESR45R	3.25mm	45mm	1.5mm
	AESR60R	3.25mm	60mm	1.5mm
	AESR60P	4.0mm	60mm	1.8mm
	AESR60B	5.0mm	60mm	2.2mm

### MRI SAFETY INFORMATION

The AEON™ Endoscopic Stapler (including the implantable Titanium staples) is MR Unsafe.

### INDICATIONS

The AEON™ Endoscopic Stapler has applications in general, abdominal, gynecologic, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses.

**NOTE:** The AEON™ Endoscopic Stapler Handle is compatible with AEON™ Endoscopic Stapler Reloads 2.25mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, 4.0mm/60mm, and 5.0mm/60mm.

**NOTE:** The AEON™ Endoscopic Stapler Handles are also compatible with the following Medtronic Covidien Stapler Reloads:

- 030412 Endo GIA™ Universal Straight 60 - 2.5 Loading Unit
- 030451 Endo GIA™ Universal Reticulator™ 30 - 2.5 Loading Unit
- 030454 Endo GIA™ Universal Reticulator™ 45 - 2.5 Loading Unit
- 030457 Endo GIA™ Universal Reticulator™ 60 - 2.5 Loading Unit

**NOTE:** The AEON™ Endoscopic Stapler Reloads 2.25mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, 4.0mm/60mm, and 5.0mm/60mm are compatible with the following Medtronic Covidien Stapler Handles:

030403 Endo GIA™ Universal Stapler

EGIAUXL Endo GIA™ Ultra Universal XL Stapler

SIGPHANDLE Signia™ Stapling System handle and SIGADAPTXL Signia™ Linear Adapter XL

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

**WARNING:** The AEON™ Endoscopic Stapler Handle is provided **STERILE** and intended for use in a **SINGLE PROCEDURE ONLY**. **DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS.**

**WARNING:** The AEON™ Endoscopic Stapler Reload is provided **STERILE** and intended for **SINGLE USE ONLY**. **DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS.** Reuse, re-processing, or re-sterilization may compromise device integrity and could lead to patient injury, illness, or death.

**WARNING:** Ensure that only structures to be cut and stapled are within the stapler jaws. Unintentional transection of tissue could lead to patient injury, illness, or death.

## **CONTRAINDICATIONS**

- 1) Do not use the AEON™ Endoscopic Stapler 2.25 mm or 2.5mm staples on the aorta, any tissue that compresses to less than 1.0 mm in thickness, or any tissue that does not comfortably compress to 1.0 mm.
- 2) Do not use the AEON™ Endoscopic Stapler 3.25 mm staples on the aorta, any tissue that compresses to less than 1.5 mm in thickness, or any tissue that does not comfortably compress to 1.5 mm.
- 3) Do not use the AEON™ Endoscopic 4.0 mm staples on the aorta, any tissue that compresses to less than 1.8 mm in thickness, or any tissue that does not comfortably compress to 1.8 mm.
- 4) Do not use the AEON™ Endoscopic 5.0 mm staples on the aorta, any tissue that compresses to less than 2.2 mm in thickness, or any tissue that does not comfortably compress to 2.2 mm.
- 5) The AEON™ Endoscopic Stapler should not be used on tissue where compressibility of the tissue could be destructive, such as the liver or spleen.
- 6) Do not use the AEON™ Endoscopic Stapler where hemostasis cannot be verified visually after application.

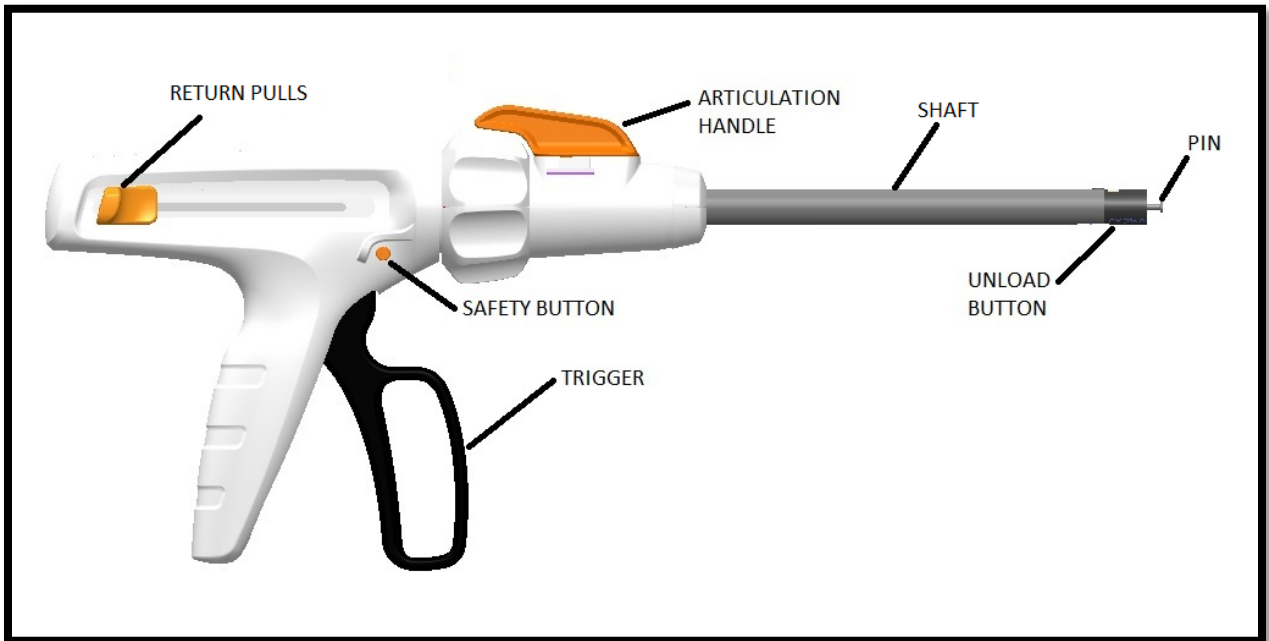
## **WARNINGS**

- 1) Inspect the tissue thickness before applying the stapler to the tissue. Tissue that is overly thick or thin may result in unacceptable staple formation.
- 2) The stapler will cut and staple any tissue, vessel, or other structure included in the jaws. Ensure that only structures to be cut and stapled are within the stapler jaws.
- 3) Ensure tissue has not extended beyond the tissue stop proximally. Tissue forced into the instrument proximal to the tissue stop may be transected without stapling.
- 4) Ensure that no obstructions, such as clips, are incorporated into the stapler jaws before closing the jaws and firing. Applying staples over an obstruction may result in incomplete transection and/or incorrectly formed staples.
- 5) Ensure that the Stapler Reload is completely fired. Failure to completely fire the Stapler Reload will result in an incomplete cut and/or incomplete staple formation, which may result in inadequate hemostasis and/or leakage.
- 6) After firing the stapler, always inspect the staple line and the surrounding site for hemostasis or leakage. Minor bleeding or leakage may be controlled by electrocautery or manual sutures.
- 7) Endoscopic procedures using this device should only be performed by physicians having adequate training with endoscopic surgical techniques.
- 8) Electrosurgical and laser procedures involving the use of this device should only be performed by physicians having adequate training with these techniques. Verify compatibility of all instruments and accessories used in the procedure to ensure that electrical isolation or grounding is not compromised.
- 9) The AEON™ Endoscopic Stapler Handle is provided STERILE and intended for use in a SINGLE PROCEDURE ONLY. The AEON™ Endoscopic Stapler Reload is provided STERILE and intended for SINGLE USE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS. Reuse, even after re-sterilization, may create a risk of contamination and lead to patient infection. Reuse, re-processing, or re-sterilization may compromise device integrity and could lead to patient injury, illness, or death.

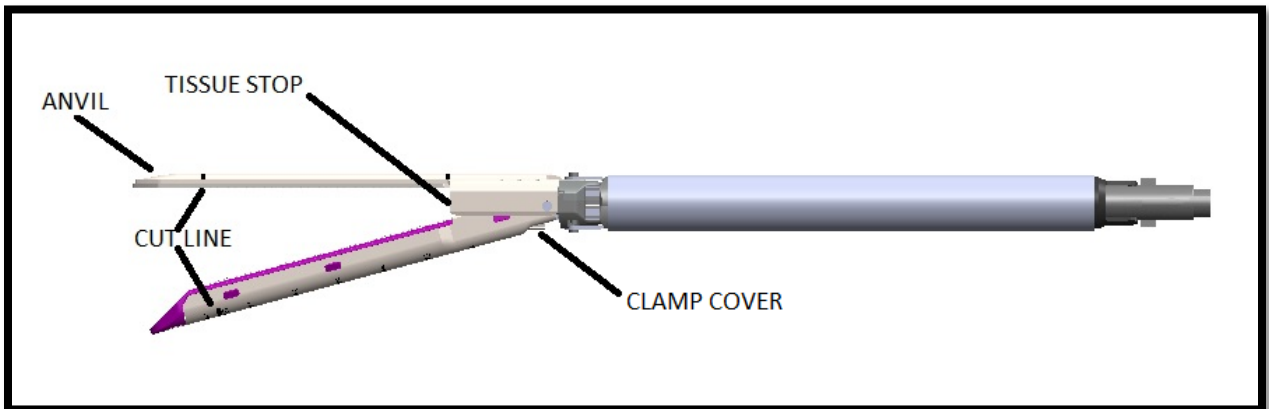
## **PRECAUTIONS**

- 1) Preoperative radiotherapy may result in changes to tissue thickness or composition. Consideration should be given to any pre-surgical treatment in selection of staple size.
- 2) Any tissue extending beyond the cut line will not be transected. Placement of tissue proximal to the tissue stops on the Stapler Reload may result in stapler malfunction.
- 3) Ensure that provisions are made for proximal and distal control before using the stapler on major vessels.
- 4) Compatibility of staple line reinforcement material with the AEON™ Endoscopic Stapler Reload has not been determined. If reinforcement is used, always include the combined thickness of both the tissue and the reinforcement material when choosing the proper Stapler Reload.
- 5) Do not exceed 25 firings for a single Stapler Handle during a single procedure. Exceeding the Stapler Handle firing limit may result in device malfunction.
- 6) Do not use the stapler on ischemic or necrotic tissue.

**STAPLER HANDLE SCHEMATIC:**



**STAPLER RELOAD SCHEMATIC:**



## INSTRUCTIONS FOR LOADING

**WARNING:** Select a Stapler Reload with the appropriate staple size for the tissue thickness. Overly thick or thin tissue may result in unacceptable staple formation. If reinforcement is used, always include the combined thickness of both the tissue and the reinforcement material when choosing the proper Stapler Reload.

**NOTE:** The AEON™ Endoscopic Stapler Handle and AEON™ Endoscopic Stapler Reloads 2.25mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, and 4.0mm/60mm are designed for introduction through a 12mm trocar, or larger with use of a converter. The AEON™ Endoscopic Stapler Reload 5.0mm/60mm must be inserted through a 15mm trocar.

**NOTE:** When using the instrument with a 5.0mm/60mm reload, the instrument **MUST** be inserted into a 15mm trocar. A smaller size trocar will not accept the 5.0mm/60mm reload.

**NOTE:** Do not attempt to remove the yellow shipping wedge from the Stapler Reload until after the Stapler Reload is loaded onto the Stapler Handle. Removing the shipping wedge from the Stapler Reload before the Stapler Reload is loaded onto the Stapler Handle may cause device malfunction.

**NOTE:** Remove the protective shipping cap from the end of the Stapler Handle before use.

- 1) The Stapler Reload is packaged in the open position – do not attempt to close the Stapler Reload jaws.
- 2) Remove the protective shipping cap from the distal end of the Stapler Handle.
- 3) Ensure that the Return Pulls on the device are fully retracted to the proximal position and that the Articulation Handle is centered on the device.
- 4) To load the Stapler Reload, first align the loading arrow on the distal end of the Stapler Handle with the loading arrow on the proximal end of the Stapler Reload.
- 5) With the loading arrows aligned, Insert the Stapler Reload over the Pin extending from the distal end of the Stapler Handle.
- 6) Twist the Stapler Reload clockwise approximately 45° to lock into place.

**NOTE:** Remove the yellow shipping wedge before closing the Stapler Reload jaws.

- 7) Remove the yellow shipping wedge from the Stapler Reload before confirming proper loading and inserting the device into the trocar.
- 8) To confirm proper loading, squeeze the Stapler Handle Trigger through a full stroke once to close the jaws. Retract the Return Pulls and confirm that the stapler jaws open fully.

## INSTRUCTIONS FOR UNLOADING

- 1) In order to unload the Stapler Reload from the Stapler Handle, the Return Pulls on the Stapler Handle must be fully retracted to the proximal position and the Articulation Handle must be centered on the device.
- 2) To unload the Stapler Reload, activate the Unload Button on the distal end of the Stapler Handle by sliding proximally.
- 3) While holding the Unload Button in the proximal position, rotate the Stapler Reload approximately 45° and pull distally until it disengages from the Stapler Handle.
- 4) Release the Unload Button.



## INSTRUCTIONS FOR USE

**NOTE:** Ensure that stapler reload jaws are closed prior to introducing the stapler into the trocar.

- 1) Squeeze the Stapler Handle Trigger through a full stroke once to close the jaws before inserting into the Trocar.
- 2) Insert the stapler into an appropriately-sized trocar and open the stapler jaws by retracting the Return Pulls fully to the proximal position.

**NOTE:** The stapler anvil must be completely visible past the distal end of the trocar prior to opening the reload jaws within the body cavity.

**NOTE:** Do not squeeze the Stapler Handle Trigger while retracting the Return Pulls.

The AEON™ Endoscopic Stapler Handle shaft can rotate 360° in either direction, and can articulate the Stapler Reload jaws to pre-set positions approximately 22° and 45° in either direction Left-Right using the Articulation Handle.

- 3) Apply the Stapler Reload jaws to the tissue to be transected. The device will not cut tissue beyond the Cut Line indicated on both sides of the jaws. More than one Stapler Reload application may be required for tissue exceeding the length of the staple line (30mm, 45mm, or 60mm).
- 4) Close the jaws of the device across the tissue to be transected by activating the Stapler Handle Trigger through a full stroke. The jaws may be repositioned if necessary by retracting the Return Pulls proximally to open the jaws, repositioning, and squeezing the Trigger to close the jaws.

**WARNING: Ensure that only structures to be cut and stapled are within the stapler jaws. Unintentional transection of tissue could lead to patient injury, illness, or death.**

**WARNING: Ensure that no obstructions, such as clips, are incorporated into the stapler jaws before application. Applying staples over an obstruction may result in incomplete transection and/or incorrectly formed staples.**

**WARNING: Ensure tissue has not extended beyond the tissue stop proximally. Tissue forced into the instrument proximal to the tissue stop may be transected without stapling.**

**CAUTION: Any tissue extending beyond the cut line will not be transected. Placement of tissue proximal to the tissue stops (on the reload) may result in stapler malfunction.**

- 5) After closing the jaws across the tissue to be transected, the Safety Button must be activated by pressing from either side of the Stapler Handle before firing.
- 6) After activating the Safety Button, the device is fired by pulling on the Trigger to commence transecting the tissue while simultaneously forming staples. Squeeze the Trigger sequentially until the Stapler Reload Clamp Cover reaches the distal end of the jaws and the Stapler Handle locks. The number of sequential squeezes is dependent upon the length of the Stapler Reload staple line (30mm, 45mm, or 60mm).

**WARNING: Ensure that the Stapler Reload is completely fired. Failure to completely fire the Stapler Reload will result in an incomplete cut and/or incomplete staple formation, which may result in inadequate hemostasis and/or leakage.**

**NOTE:** A safety interlock prevents an empty Stapler Reload from being fired twice. Do not attempt to override the safety interlock, as overriding the safety interlock will cause device malfunction.

- 7) Once the device has been fully-fired, open the jaws by retracting the Return Pulls completely back to the proximal position. Gently remove the device from the tissue and inspect the staple line for hemostasis.
- 8) After removing the device from the tissue, close the stapler jaws by squeezing once on the Trigger through a complete stroke and center the Articulation Handle before removing the device from the body cavity.
- 9) Remove the device from the body cavity and unload the Stapler Reload.
- 10) Dispose of used instruments in accordance with the end-user's medical and biological waste disposal requirements.

**NOTE:** Ensure that the Articulation Handle is centered on the device before removing the stapler from the trocar.

**WARNING:** After firing the stapler, always inspect the staple line and the surrounding site for hemostasis or leakage. Minor bleeding or leakage may be controlled by electrocautery or manual sutures.

**CAUTION:** Do not exceed 25 firings for a single Stapler Handle during a single procedure. Exceeding the Stapler Handle firing limit may result in device malfunction.

**STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.**



**SINGLE  
PATIENT  
USE**



**DO NOT  
RESTERILIZE**



**DO NOT USE  
PACKAGE IF  
DAMAGED**



**KEEP  
DRY**



**CONSULT  
INSTRUCTIONS  
FOR USE**



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